Requires no special expertise to use, so that workers or their local health professionals can use the device.

Be immunoassay-based, in order to get sufficient sensitivity and selectivity.

Be self-contained, i.e., does not require any instrumentation for analysis.

Be produced easily and inexpensively and be readily available to workers.

Applicants will be judged according to the following criteria:

1. Adequacy and technical capabilities to develop the desired technologies and product;

2. Ability to develop, produce, market, and support the device; and

3. Ability to complete the CRADA in a timely fashion.

This CRADA is proposed and implemented under the 1986 Federal Technology Transfer Act: Public Law 99–502.

The response must be made to: Theodore F. Schoenborn, Technology Transfer Coordinator, National Institute for Occupational Safety and Health, CDC, 4676 Columbia Parkway, Mailstop R–2, Cincinnati, Ohio 45226 Telephone 513–841–4305, Fax 513–841–4500.

Dated: January 17, 1996.

Linda Rosenstock,

Director, National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–950 Filed 1–23–96; 8:45 am]

BILLING CODE 4163–19–P

Food and Drug Administration

[Docket No. 95D–0166]

Quality Assurance Program Audits and Inspections; Compliance Policy Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised Compliance Policy Guide (CPG) 7151.02 entitled ''FDA Access to Results of Quality Assurance Program Audits and Inspections.'' This revised CPG provides general policy and guidance to FDA field and headquarters staff (engaged in the inspection and investigation of any regulated entity) regarding routine access to review reports or copying of records that result from the entity's audits and inspections of a written quality assurance program.

ADDRESSES: CPG 7151.02 is available for public examination in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Tom M. Chin, Office of Enforcement (HFC–230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0410.

SUPPLEMENTARY INFORMATION: FDA has revised CPG 7151.02 entitled ''FDA Access to Results of Quality Assurance Program Audits and Inspections.'' This CPG was revised to provide general policy and clearer guidance to FDA field and headquarters staff (engaged in the inspection and investigation of any regulated entity) regarding routine access to review reports or copying of records that result from the entity's audits and inspections of a written quality assurance program.

The statements made in CPG 7151.02 are not intended to bind the courts, the public, or FDA, or to create or confer any rights, privileges, immunities, or benefits on or for any private person, but are intended merely for internal FDA guidance.

Dated: January 3, 1996.

Gary Dykstra

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 96–940 Filed 1–23–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95D–0386]

Guidance for Industry; Content and Format of Investigational New Drug Applications (IND's) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-Derived Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Guidance for Industry; Content and Format of Investigational New Drug Applications (IND's) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-derived Products.'' The guidance clarifies data requirement issues related to the initial entry of an unapproved drug into human studies in the United States. The guidance is intended to expedite the entry of new drugs into clinical studies by eliminating ambiguities in IND requirements and by decreasing inconsistencies in IND reviews.

DATES: Written comments on the guidance may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the guidance entitled ''Guidance for Industry; Content and Format of Investigational New Drug Applications (IND's) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-derived Products'' to the Consumer Affairs Branch (formerly the CDER Executive Secretariat Staff), Center for Drug Evaluation and Research (HFD–210), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, or the Congressional and Consumer Affairs Branch, Center for Biologics Evaluation and Research (HFM–12), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–594–1800 or 800–835–4709. Send two self-addressed adhesive labels to assist the offices in processing your requests. A copy of the guidance document is also available from CDER's FAX On Demand. To obtain a copy from FAX On Demand, call 1–800–342–2722 or locally 301–827–0577. An electronic version of the guidance document is also available via Internet. Requesting persons should connect to the CDER file transfer protocol (FTP) server (CDVS2.CDER.FDA.GOV) using the FTP protocol. The guidance is available in WordPerfect versions 5.2 and 6.0. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Murray M. Lumpkin, Center for Drug Evaluation and Research (HFD–2), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20852, 301–594–6740, or Rebecca Devine, Center for Biologics Evaluation and Research (HFM–10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance entitled ''Guidance for Industry; Content and Format of Investigational New Drug Applications (IND's) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-derived Products.'' Any use in humans in the United States of a drug product not